DEPARTMENT OF HEALTH AND HUMAN SERVICES

1112 '00 JUN 15 JUNO 357 2000

Joseph C. Griffin, III
Vice President of Regulatory Affairs
EP MedSystems, Inc.
100 Stierli Court, Suite 107
Mt. Arlington, New Jersey 07856

Re: Docket No. 00P-1286
Electrophysiology Catheters

Dear Mr. Griffin:

This responds to your citizen petition, dated April 26, 2000, requesting a variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables for your firm's electrophysiology (EP) catheters. Your petition asked that you be allowed to continue distributing EP catheters with unprotected 2 mm pin connectors until August 9, 2000. From a subsequent letter from Mr. James E. Kuhn, Jr., dated May 22, 2000, I understand that your request is limited to only those non-compliant EP catheters that are in your current finished goods inventory. It no longer includes the threshold (extension) cables identified in your original request. Your petition noted that you have experienced unexpected delays in securing adequate quantities of the protected pin connector needed to bring your EP catheters into compliance with the performance standard. You also noted the potential for product shortages in healthcare facilities, if your variance is not granted.

Your petition is hereby granted, but only because we are concerned about the potential for shortages of EP catheters in healthcare facilities. As a condition of this variance approval, you are requested to prepare a notification letter to healthcare facilities that are your current customers. You may wish to include a copy of this approved variance. Healthcare facilities may not continue to use non-compliant EP catheters indefinitely. Your letter should remind your customers of their obligation to be in full compliance with the performance standard by August 9, 2000, and should provide your anticipated delivery schedule for compliant EP catheters. Healthcare facilities must discontinue use of non-compliant EP catheters as soon as new compliant EP catheters are received. Your notification letter should issue to your customers within 15 days of your receipt of this letter, with a copy submitted to the Office of Compliance, HFZ-340, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, Maryland 20850.

00P-1286

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HFZ-401	[illegible]	5/30/00						
HFZ-16	[illegible]	5/30/00						
HFZ-15	Sheehan	5/30/00						
HFZ-27	KAHAN	6/6/00						

Finally, you raised concern about the excessive cost to mount adapters permanently on your equipment. It is our understanding that your lead wire supplier also provides a suitable 2 mm adapter that requires a tool for installation and removal. The cost of their adapter is approximately $5.00. We understand that because of high demand, these adapters are currently in short supply. However, over the next several months, they may provide a viable alternative to your customers who do not choose to exchange their equipment.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health